



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/689,381

10/20/2003

David A. Griffith

PC25033A

3591

28523

7590

06/01/2006

PFIZER INC.  
PATENT DEPARTMENT, MS8260-1611  
EASTERN POINT ROAD  
GROTON, CT 06340

EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/689,381	Applicant(s) GRIFFITH, DAVID A.	
	Examiner Mark L. Berch	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 411, 453, O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-51, 53 and 77-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 50, 51, 53 and 77 is/are rejected.
- 7) ☒ Claim(s) 3-49 and 78-84 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/18/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1624

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 50-51, 53, 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6841549.

Note field 87, giving publication date of 1/11/2001.

See example 14. This compound differs from the claims only in that it lacks the 9-heteroaryl feature required. However, the definition of R3 in the reference includes both choices, and there are numerous examples of compounds with exactly that, e.g. 11-12, 54-55, 58-60 and many more. Thus, the reference teaches these choices as alternatively useable for the invention. Alternatively, see e.g. 11-12, 54-55, 58-60. These differ from the claims only in that they have amino or dimethylamino instead of pyrrolidino. However, the definition for R1 clearly embraces NR4R5 forming a ring. See e.g. the definition for R1 is claim 1 of the patent, or at column 15, lines 32-37. Example 14 provides clear motivation to make the specific choice of pyrrolidino. In other words, the reference exemplifies both features, albeit no one species has both, and hence the reference is applied under 35 USC 103 rather than 102. With regard to claims 50-53, the reference teaches treatment of

Art Unit: 1624

diabetes, and since obesity is a prime cause for DM, it would be obvious to use the agents of the reference in combination with any known type of anti-obesity drug.

The traverse is unpersuasive. Applicants raise two arguments:

A. The primary amino group is preferred, not a heterocycle, because “the vast majority” of the compounds do have a primary amino. The fact that the vast majority are primary amino does not make it preferred, but even if it did, that argument is not legally sufficient.

A reference is available for all that it teaches, not just the best or even the preferred embodiments. In this regard, see *In re Lamberti*, 192 USPQ 278, 280; *In re Boe*, 148 USPQ 507, 510; *In re Fracalossi*, 215 USPQ 569, 570, and other cases cited in MPEP 2123.

B. The reference had a completely different utility. It is correct that the reference is drawn to A2 antagonists and the present invention is drawn to CB-1 antagonists. The fact that the prior art compounds are not disclosed to have this property is not enough to avoid an obviousness rejection. Applicants must show that the prior art compounds do not actually have the property disclosed here, by suitable comparative testing. Cf *In re Dillon*, 16

USPQ2d 1897, 1901; *In re Hoch*, 166 USPQ 406; *Brown v. Gottshalk*, 179 USPQ 65; *In re Murch*, 175 USPQ 430. Note also *In re Lintner*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

It is not necessary for the prior art to have recognition or appreciation of this activity for other than method of use claims. See also *In re Shetty*, 195 USPQ 753 for a case where the prior art did not teach applicants' exact utility. Note also *In re Baxter Travenol Labs*, 21 USPQ2d 1281, 1285 which states, “Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention.” Note also *In re Ona*, 38 USPQ2d 1597 (“...all benefits need not be explicitly disclosed to render the claims unpatentable ...”). That is, mere recognition of latent properties in the prior art does not

Art Unit: 1624

render not obvious an otherwise known invention, *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA1979) "The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." *Ex parte Obiaya*, 227 USPQ 58, 60 (Board held asserted advantage would flow naturally from following the suggestion of the prior art.). See also *Lantech Inc. v. Kaufman Co. of Ohio Inc.*, 12 USPQ2d 1076, 1077 (Fed. Cir. 1989), cert. denied, 493 U.S. 1058 (1990) (unpublished - not citable as precedent) ("The recitation of an additional advantage associated with doing what the prior art suggests does not lend patentability to an otherwise unpatentable invention."). See MPEP 2144 and 2145.

C. Applicants disagree with the statement by the examiner that "obesity is a prime cause for DM". Insofar as type-2 DM is concerned, this traverse is not agreed with. It is beyond question that Type 2 diabetes has an especially strong association with diabetes, and substantial weight loss can markedly improve type 2 diabetes (note first sentence of Hollander reference). To refute applicants' argument, there is cited 3 references. The Hollander and Miles references both show that Orlistat, an example of an FDA-approved anti-obesity drug, is helpful in treating type 2 diabetes (i.e. gives improved glycemic control). Incidentally, the metformin in Miles is itself a type 2 diabetes drug, and has been shown to cause weight loss in overweight adults. Similarly, Fujioka shows that another anti-obesity drug, sibutramine in type 2 diabetes patients showed improvements in fasting plasma glucose and in fasting insulin. This establishes that one of ordinary skill in the art would find it obvious to use anti-obesity drugs as part of treatment of type 2 diabetes.

***Claim Objections***

Claims 3-49, 78-84 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch  
Primary Examiner  
Art Unit 1624

5/25/06